In the United States Court of Federal Claims

No. 20-499C

(Filed under seal: June 17, 2022)
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GILEAD SCIENCES, INC., Plaintiff, **v.** **UNITED STATES,** Defendant.	Contract case involving a patent dispute; pre-trial motions *in limine*

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OPINION AND ORDER[1]

LETTOW, Senior Judge.

In anticipation of trial, pending before the court in this contract dispute case are four motions *in limine* and one motion to strike. Plaintiff Gilead Sciences, Inc. ("Gilead") has sued defendant United States ("the government") for breach of contract, alleging that the Centers for Disease Control and Prevention ("CDC") violated the terms of four Material Transfer Agreements ("MTAs") and two Clinical Trial Agreements ("CTAs"). *See* First Am. Compl., ECF No. 33. This action is closely tied to a patent infringement case pending in the United States District Court for the District of Delaware styled *United States v. Gilead Sciences, Inc.*,

[1] Because of the protective order entered in this case, this opinion was initially filed under seal. The parties were requested to review the decision and provide proposed redactions of any confidential or proprietary information. No redactions were requested.

No. 19-2103MN (D. Del., filed Nov. 5, 2019). Discovery in that action and this one has been coordinated by the parties, but the case before that court is not scheduled to proceed to trial until May 2023. Hr'g Tr. 9:25 to 10:19 (Apr. 26, 2022).

In anticipation of the trial before this court, Gilead has filed three motions *in limine*, and the government likewise has filed one.[2] Each motion seeks to exclude evidence from the trial scheduled to begin June 23, 2022. Specifically, Gilead seeks to exclude evidence relating to the quantum of damages, and evidence of public disclosures or third-party publications (and related communications and testimony) as proof of "notification" to Gilead, as well as to exclude the testimony of government expert Kimberly Schenk (whose opinion Gilead alleges is directed to damages only). *See* Pl.'s Mot. *in Limine* re Quantum of Damages ("Pl.'s Damages Mot."), ECF No. 75; Pl.'s Mot. *in Limine* re Public Documents ("Pl.'s Notification Mot."), ECF No. 74; and Pl.'s Mot. *in Limine* re Kimberly Schenk ("Pl.'s Schenk Mot."), ECF No. 73. Gilead has also filed a motion to strike the supplemental expert report of Ms. Schenk (which was included in the government's opposition to Gilead's related motion *in limine*) on the grounds that it is untimely and irrelevant. Pl.'s Mot. to Strike Supp. Rep. of Kimberly Schenk ("Pl.'s Mot. to Strike"), ECF No. 93. In turn, the government seeks to exclude the testimony of Gilead experts Wesley D. Blakeslee and Connie L. Celum regarding whether the claimed inventions satisfy the requirement in the agreements that they "derive" from the relevant clinical studies. *See* Def.'s Mot. *in Limine* re Derivation ("Def.'s Derivation Mot."), ECF No. 72. After briefing was completed, the court held a hearing on June 13, 2022. The motions are ready for disposition.

BACKGROUND[3]

Gilead, a biopharmaceutical company at the forefront of developing effective treatments for HIV, *see* First Am. Compl. ¶ 3, has collaborated with CDC "on various research studies relating to the use of antiretroviral agents for prevention of HIV-1." First Am. Compl. ¶ 4. This lawsuit centers on six agreements between Gilead and CDC concerning drugs used for HIV-1 pre-exposure prophylaxis ("HIV PrEP"). Between 2004 and 2014, Gilead and CDC entered into six separate agreements—four MTAs and two CTAs—to collaborate on research studies relating to the use of certain drugs to prevent HIV. First Am. Compl. ¶¶ 5-6. Via the MTAs, Gilead provided CDC "with significant quantities of Gilead compounds free of charge." First Am. Compl. ¶¶ 6, 45. In return, the government was required to disclose to Gilead all "results, data, and other information or materials derived from" the government's use of Gilead's drugs. First Am. Compl., Ex. 4 (May 27, 2004 MTA) ¶ 8, ECF No. 34-4. Relevant here, the government was also required to "promptly notify" Gilead of "any Inventions" derived from work performed under the agreements. First Am. Compl. ¶ 6. "Inventions" were defined in each MTA as "any inventions, discoveries and ideas that are made, conceived or reduced to practice." First Am.

[2] The government also filed a motion *in limine* to exclude the testimony of Gilead expert Robert Stoll. *See* Def.'s Mot. *in Limine* re Robert Stoll, ECF No. 71. Gilead has clarified that the motion is now moot because it will not be calling Mr. Stoll as a witness at trial. *See* Joint Notice of June 10, 2022, ECF No. 98. As such, that motion is DENIED AS MOOT.

[3] The recitations that follow do not constitute findings of fact but rather are recitals attendant to the pending motions and reflect matters drawn from the complaint, the parties' briefs, and records and documents appended to the complaint and briefs.

Compl., Ex. 4 ¶ 8. Per the agreements, the CDC "agree[d] to give serious and reasonable consideration to [Gilead's] request for a non-exclusive or exclusive license." First Am. Compl., Ex. 4 ¶ 8.

The parties also entered into two CTAs. The first CTA stated that Gilead would provide antiviral products for a clinical trial in the United States called CDC 4323. First Am. Compl., Ex. 27 (Aug. 6, 2006 CTA), ECF No. 34-27.[4] The second CTA stated that Gilead would provide antiviral products for a clinical trial in Botswana. First Am. Compl., Ex. 13 (Nov. 1, 2004 CTA), ECF No. 34-13.[5] Both CTAs stipulated that CDC would "not . . . seek patent protection in connection with any inventions that derive from the use of the Study Drug[s] in the Trial[s]," and that CDC was "to put the results of the Trial[s], patentable or otherwise, in the public domain for all to use without obligation or compensation to CDC." First Am. Compl., Ex. 27, ¶ 7.

Nonetheless, in February 2006, CDC took steps to patent inventions "related to purported inventions that CDC made in the course of the research conducted under the MTAs, . . . using the compounds that Gilead provided under the MTAs," by filing Provisional Patent Application No. 60/764,811 with the United States Patent and Trademark Office. First Am. Compl. ¶ 11. In 2007, CDC filed non-provisional Patent Application No. 11/669,547, which claimed priority to the previous provisional application. First Am. Compl. ¶ 11. Gilead alleges it was not notified of such actions. First Am. Compl. ¶ 13. Years later, after a number of rejections by the Patent and Trademark Office, several patents did eventually issue to the government, beginning in 2015.[6] Gilead, having received approval from the Food and Drug Administration on July 16, 2012, for the use of the drug Truvada for HIV PrEP, had already begun providing the drug to the public. *See* First Am. Compl. ¶ 15. The government notified Gilead on March 11, 2016, that Truvada "may be covered" by patents "recently obtained" by CDC. First Am. Compl., Ex. 26 (Mar. 11, 2016 correspondence) at 1, ECF No. 34-26.[7] Gilead countered that the government had breached their agreements and that the patents were not valid. First Am. Compl. ¶ 110.

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[4] The clinical trial was otherwise titled as "Phase II Extended Safety of Tenofovir Disoproxil Fumarate (TDF) among HIV-I Negative Men who have Sex with Men." First Am. Compl., Ex. 27. This study will be referred to as the "Extended Safety Study" herein. TDF is a drug marketed by Gilead as Viread. Pl.'s Opp'n to Def.'s Derivation Mot. at 2 n.1, ECF No. 86.

[5] The clinical trial was called "Study of the Safety and Efficacy of Daily Tenofovir Disoproxil Fumarate ('TDF') for the Prevention of HIV Infection in Heterosexually-Active Young adults in Botswana." First Am. Compl., Ex. 13. Although the original study assessed the use of TDF alone, the study drug was subsequently changed to the drug Gilead markets as Truvada. Pl.'s Opp'n to Def.'s Derivation Mot. at 3 n.2. This study will be referred to as the "Botswana Study."

[6] Those patents are Nos. 9,044,509 (issued June 2, 2015); 9,579,333 (issued Feb. 28, 2017); 9,937,191 (issued Apr. 10, 2018); and 10,335,423 (issued July 2, 2019). *See* First Am. Compl. ¶ 12.

[7] Gilead alleges that CDC failed to "promptly notify" Gilead of any "Inventions" arising from the MTAs and CTAs or its plans to seek patent protection until October 2014 at the earliest. First Am. Compl. ¶ 13.

On November 6, 2019, the government filed suit against Gilead in the United States District Court for the District of Delaware. *See United States v. Gilead Sciences, Inc*., No. 19-2103MN (D. Del., filed Nov. 6, 2019). The government alleges in the Delaware lawsuit that Gilead infringed its patents by selling and promoting Truvada and a related drug, Descovy, for HIV PrEP. First Am. Compl. ¶ 115. Subsequently, on April 24, 2020, Gilead filed suit in this court, alleging breach of the MTAs and CTAs. *See* Compl., ECF No. 1. Since that time, the court has held that it possessed jurisdiction over the case and declined to dismiss the action. *See Gilead Sciences, Inc. v. United States*, 151 Fed. Cl. 742 (2020); *Gilead Sciences, Inc. v. United States*, 155 Fed. Cl. 336 (2021). The court bifurcated the issues of liability and damages, while acknowledging that "some indication of damages" would be required during the liability phase of the case. Hr'g Tr. 26:2-13; 36:23-24 (Apr. 6, 2021).

Discovery for the liability phase closed April 21, 2022 (with the exception of one deposition), and the parties have entered the pre-trial stage for the liability portion of the bifurcated litigation. Each party now seeks to exclude certain evidence from the liability trial. The specifics of each motion will be addressed *infra*.

ANALYSIS

At trial, Gilead seeks to prove the government's liability for breach of the MTAs and CTAs that governed the provision of Gilead-developed drugs for clinical study. To recover for breach of contract, Gilead must establish four elements: "(1) a valid contract between the parties, (2) an obligation or duty arising out of the contract, (3) a breach of that duty, and (4) damages caused by the breach." *San Carlos Irrigation & Drainage Dist. v. United States*, 877 F.2d 957, 959 (Fed. Cir. 1989). Gilead bears the burden of proving each element by a preponderance of the evidence. *See Fields v. United States*, 147 Fed. Cl. 352, 355 (2020). As to the last element, Gilead must show that "(1) the damages were reasonably foreseeable by the breaching party at the time of contracting; (2) the breach [was] a substantial causal factor in the damages; and (3) the damages are shown with reasonable certainty." *Indiana Michigan Power Co. v. United States*, 422 F.3d 1369, 1373 (Fed. Cir. 2005). The court has bifurcated the litigation, leaving the issue of damages to another day—save that Gilead must establish some proof of damages to establish liability. The parties now seek to exclude evidence on the eve of the liability trial.

A. Expert Testimony

The Federal Rules of Evidence govern the admissibility of evidence in this court. *See* 28 U.S.C. § 2503(b) ("The proceedings of the Court of Federal Claims shall be in accordance with . . . the Federal Rules of Evidence."). When evaluating the admissibility of expert testimony, Federal Rule of Evidence 702 is controlling and provides that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact . . . ; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702(a)-(d). Pursuant to Federal Rule of Evidence 104(a), a trial judge must determine "at the outset" whether an expert witness is qualified or whether his or her opinions constitute admissible evidence. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 (1993). "These matters should be established by a preponderance of proof." *Id.* at 592 n.10 (citing *Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987)).

In addition to reliability, the court must also ensure that the offered expert testimony is relevant. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999); *Daubert*, 509 U.S. at 589. "Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. Rule 702 further requires that expert testimony "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Even in the face of evidence that is both reliable and relevant, "[t]he court may exclude [such] evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. While concerns of misleading the jury "are of lesser import in a bench trial, . . . the *Daubert* standards of relevance and reliability for [expert] evidence must nevertheless be met." *Seaboard Lumber Co. v. United States*, 308 F.3d 1283, 1302 (Fed. Cir. 2002).

The motions to exclude testimony filed by the parties relate to the proposed testimony of three expert witnesses. The court will address the motions regarding these challenged witnesses in turn.

1. Evidence and expert testimony from Mr. Wesley Blakeslee and Dr. Connie Celum.

The government challenges as unreliable portions of the testimony of Mr. Wesley Blakeslee and Dr. Connie Celum, both of whom intend to offer opinions that the inventions claimed in the at-issue patents "derive" from the Extended Safety Study and the Botswana Study. *See generally* Def.'s Derivation Mot. Specifically, the government argues that both experts lack the requisite expertise with patents—and the patents at issue here in particular—to form a reliable opinion. *Id.* at 4, 6. Mr. Blakeslee has years of experience with technology transfer offices dealing in the types of contracts at issue in this case, and Dr. Celum is a clinical researcher who specializes in HIV research. *See* Pl.'s Opp'n to Def.'s Derivation Mot. at 1. Gilead contends the experts' expertise and experience qualify them to provide the testimony to be offered. *Id.*

(i.) Mr. Blakeslee.

Mr. Blakeslee opines that "parties entering into a clinical trial agreement would understand that the intent of the contract was to ensure that the commercial entity, here Gilead, would be able to retain its freedom to operate and use its own products for any purpose, including PrEP." Def.'s Derivation Mot., Ex. 2 (Blakeslee Report) ¶ 3b, ECF No. 72-2. The government argues that Mr. Blakeslee intends to testify that the '811 provisional patent application and the '547 non-provisional patent application posited different claims than those embodied in the issued patents, a position it argues Mr. Blakeslee cannot offer due to a lack of expertise and unfamiliarity with the at-issue patents. Def.'s Derivation Mot. at 3. Specifically, the government contends that Mr. Blakeslee did not make an "assessment of the scope of the

claims, the disclosures of the '811 [p]rovisional or the '547 [a]pplication, or whether the issued claims contained 'new matter.'" *Id.* (citing Ex. 3 (Blakeslee Depo. Tr.), ECF No. 72-3). Gilead argues that Mr. Blakeslee is offering his opinion based on the language of the contracts at issue, which requires little or no analysis of the patents. Pl.'s Opp'n to Def.'s Derivation Mot. at 6-7.

Generally, expert testimony on issues of law is inadmissible. *See Sparton Corp. v. United States*, 77 Fed. Cl. 1, 7-8 (2007). But "[g]overnment contract experts have been allowed to testify in federal courts regarding the meaning of contract terms when the meaning depends on trade practice." *Id.* at 8 (summarizing cases). According to Federal Rule of Evidence 401, "[e]vidence is relevant if . . . it has any tendency to make a fact more or less probable" and "the fact is of consequence in determining the action." Fed. R. Evid. 401; *see also* Fed. R. Evid. 402 (relevant evidence is admissible unless barred by some source of law). Although both parties agree that "derive" should be interpreted based on its plain meaning, *see* Pl.'s Opp'n to Def.'s Derivation Mot. at 3 n.3; Def.'s Reply to Def.'s Derivation Mot. at 2, ECF No. 88, it would be useful to the court to hear testimony on the use of the term in the context of technology transfer agreements specifically. Mr. Blakeslee is qualified to provide that testimony based on his years as a technology transfer professional. While the government contends that Mr. Blakeslee is unqualified to offer his testimony because of his lack of experience with patents, that is not the focus of his opinion. Where his opinion is based on the contractual language and his experience as a technology transfer professional, it is reliable.

As for Mr. Blakeslee's opinions "that the issued claims of the [at-issue p]atents are different than those filed with the '811 [p]rovisional and are not supported by the disclosures of the '547 [a]pplication," Def.'s Derivation Mot. at 4, they too are relevant and reliable. It is a core issue of this case as to whether there is a causal nexus between the agreements, the studies, and the at-issue patents. Mr. Blakeslee specified during his deposition testimony that he was not offering testimony as a patent expert. Def.'s Derivation Mot. at 4 (citing *id.*, Ex. 3). The language of Mr. Blakeslee's opinion is rooted in the language of the contracts, not the patents. *See, e.g., id.*, Ex. 1 (Blakeslee Reply Rep.) at 12, ECF No. 72-1 ("The disclosure of results of animal studies in the 2006 Provisional Application does not change the fact that [the at-issue studies would have provided relevant data.] CDC was a party to all of the agreements in question (the CTAs and the MTAs), and thus at the time the 2006 Provisional Application was filed in 2006, CDC was aware of those clinical trials."). The causal nexus between the studies and the *inventions* covered by the patent is a relevant inquiry on which Mr. Blakeslee is qualified to offer an opinion as a technology transfer professional. The fact that the inventions are covered by a patent does not render their very nature and alleged derivational history outside the scope of expert testimony by someone who is not a qualified patent expert. The government's motion *in limine* to exclude this portion of Mr. Blakeslee's testimony is DENIED.

(ii.) Dr. Connie Celum.

Dr. Celum's opinion is that the "Extended Safety Study [which was the subject of the first CTA] was a crucial and foundational study for HIV PrEP involving TDF," Def.'s Derivation Mot., Ex. 7 (Dr. Celum's Reply Expert Rep.) ¶ 3, ECF No. 72-7, and had it revealed "dangers in using Gilead's drugs for PrEP, then other ongoing trials, including the one on which the government relied in prosecuting its patents (the 'iPrEx trial'), would have been paused or discontinued." Pl.'s Opp'n to Def.'s Derivation Mot. at 2 (citing Def.'s Derivation Mot., Ex. 7 ¶ 20). Dr. Celum opined that "derived" means "based on" or "foundational." Def.'s Derivation

Mot., Ex. 6 (Dr. Celum's Depo. Tr.) 49:24 to 52:5; 63:15 to 64:14, ECF No. 72-6. The government argues that Dr. Celum's opinion as to derivation of the inventions should be excluded because she lacks a factual basis to offer that opinion and her definitions are incorrect. *Id.* at 6-7. Gilead counters that Dr. Celum has extensive experience with HIV PrEP clinical studies and that the government's arguments go to the weight of Dr. Celum's opinions, not admissibility. Pl.'s Opp'n to Def.'s Derivation Mot. at 8-9.

The court agrees. The crux of the parties' disagreement on this front is how to characterize Dr. Celum's opinions and testimony. Gilead's position, as the court understands it, is that Dr. Celum's opinion is that but for the results of the Extended Safety Study, the iPrEx clinical trial would not have occurred or been completed and, following the causal chain, the inventions covered by the at-issue patents would not have been possible. The government on the other hand contends that Dr. Celum's opinions do not address the issue of "whether the CDC sought patent protection in connection with any 'inventions that derive from the use of the [s]tudy [d]rug in the [clinical t]rial.'" Def.'s Reply to Def.'s Derivation Mot. at 6. Yet, the nature and propriety of Dr. Celum's opinions in this regard are best borne out, or not, at trial. Dr. Celum has extensive experience in HIV research, *see* Def.'s Derivation Mot. at 5, which is sufficient to support a factual basis for her to opine on the causal chain, if any, between the clinical trials and the resulting inventions. What weight the court should give Dr. Celum's opinions on this issue can be established—or undermined—at trial. To the extent Dr. Celum's opinions bear on the patents at issue, the government can explore that in *voir dire*. The government's motion *in limine* to exclude portions of Dr. Celum's expert opinions is DENIED.

2. Evidence and testimony from Ms. Kimberly Schenk.

Gilead has filed two motions *in limine* that relate to the projected expert testimony of Ms. Kimberly Schenk. *See generally* Pl.'s Schenk Mot.; Pl.'s Damages Mot. Ms. Schenk is a certified public accountant who is expected to testify as to "the harms that may potentially arise from the [g]overnment's alleged breaches of four [MTAs] and two [CTAs] between the [g]overnment and Gilead." Pl.'s Schenk Mot., Ex. B at ¶ 1 (Schenk Rep.), ECF No. 73-2. Gilead seeks to exclude Ms. Schenk's testimony on foreseeability of harm, causation of harm, and the quantification of damages as unreliable and, in relation to the quantification of damages portion, that it goes beyond the scope of this phase of the litigation. Pl.'s Schenk Mot. at 1-3; Pl.'s Damages Mot. at 1. The government counters that Ms. Schenk's opinions go to "harm and threshold damages issues that are necessary for Gilead to establish liability." Def.'s Opp'n to Pl.'s Schenk Mot. at 1, ECF No. 83. To establish damages, Gilead must show that "(1) the damages were reasonably foreseeable by the breaching party at the time of contracting; (2) the breach [was] a substantial causal factor in the damages; and (3) the damages are shown with reasonable certainty." *Indiana Michigan Power Co.*, 422 F.3d at 1373. Gilead challenges Ms. Schenk's testimony on the first two factors as well as any attempt to quantify damages at this stage of the case when liability, not damages, is at issue.

(i.) Foreseeability.

As to foreseeability, Ms. Schenk opines that "[d]amages based on the cost or value of the materials transferred under the MTAs and CTAs are forms of reliance or restitution damages that were reasonably foreseeable at the time the contracts were entered. Damages based on legal fees and license fees are forms of expectation damages that were not foreseeable at the time the

MTAs and CTAs were entered." Def.'s Opp'n to Pl.'s Schenk Mot. at 10 (internal citations and formatting omitted). Gilead argues that Ms. Schenk lacks the requisite experience with MTAs and CTAs to provide a reliable expert opinion on foreseeability of damages. Pl.'s Schenk Mot. at 7. Gilead represents that Ms. Schenk is an expert in valuation of damages alone, but this argument misses the mark. "[I]f an expert is qualified to testify about a subject generally and has had training in the subject matter at issue, then the expert may offer an opinion." *Zoltek Corp. v. United States*, 95 Fed. Cl. 681, 684 (2010) (internal quotations and citations omitted). Ms. Schenk "has Bachelor's degrees in finance and economics, a Master's degree in accountancy, with a specialty in forensic accounting, has over twenty years of experience consulting . . ., and has worked in over a hundred litigation matters, many involving various types of intellectual property agreements." Def.'s Opp'n to Pl.'s Schenk Mot. at 10. These experiences and qualifications satisfy the reliability standard for Ms. Schenk to provide expert testimony on foreseeability of damages in this case, regardless of any lack of experience with MTAs and CTAs specifically.

While Gilead relies on *Smith v. Goodyear Tire & Rubber Co.*, where a witness was not qualified as an expert because he had "never been employed in any capacity dealing with the design or manufacture of tires." 495 F.3d 224, 227 (5th Cir. 2007). That case is distinguishable from the situation at hand. In *Goodyear*, the expert had no relevant experience with the subject matter, while Ms. Schenk has experience opining on damages and issues inherent in quantifying them, including whether they were foreseeable at the time of contract. Ms. Schenk's lack of experience with MTAs and CTAs goes to the weight of her opinion, but her experience in otherwise evaluating damages is sufficient to satisfy the reliability of her opinion under *Daubert*, particularly where a "witness' qualifications to render an expert opinion are . . . liberally judged." *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993).

Gilead further alleges that Ms. Schenk's opinions on foreseeability are irrelevant because they are based on incorrect legal standards by requiring the parties to have "actually fores[een] the specific sequence of events that cause Gilead's loss." Pl.'s Schenk Mot. at 10-11 (emphasis omitted). The government contends that Ms. Schenk imposed no such requirement, rather the parties simply disagree on what would have been required for the parties to foresee the claimed damages. Def.'s Opp'n to Pl.'s Schenk Mot. at 13-18. The parties seem to concur on what standard applies (that damages must be reasonably foreseeable at the time of contracting), and the true extent of their disagreement is what facts are necessary to support their positions on foreseeability and whether they actually do so. While the trial at hand is focused on liability alone at this stage, Gilead must satisfy that some damages are available to it should it prevail, and whether said damages are reasonably foreseeable is relevant to that inquiry. Gilead also challenges that Ms. Schenk's opinions as to the quantifiability of damages to a reasonable degree of certainty are inconsistent with the law. Pl.'s Schenk Mot. at 15. The government rebuffs any such inconsistency. Def.'s Opp'n to Pl.'s Schenk Mot. at 19. In short, although both parties agree on the governing law, *compare* Pl.'s Schenk Mot. at 15, *with* Def.'s Opp'n to Pl.'s Schenk Mot. at 19, they disagree on its application to the case at hand. This is an issue best suited to be determined at trial after a full presentation of the evidence. As such, Gilead's motion *in limine* to exclude Ms. Schenk's opinion on the foreseeability of damages is DENIED.

(ii.) Lack of harm.

Gilead next challenges Ms. Schenk's opinion that "a finding of harm from the breach of the MTAs requires Gilead to demonstrate that it would have done something different that is economically meaningful had the [g]overnment notified Gilead of the '811 Provisional at a prior point in time." Pl.'s Schenk Mot. at 18 (quoting Schenk's Opening Rep. ¶ 133). Gilead argues that this standard is "made-up." *Id.* The government argues that Ms. Schenk's opinion is consistent with "plaintiff's burden to show that the damages would not have occurred 'but for' the alleged breaches, which necessitate a 'comparison between the breach and non-breach worlds." Def.'s Opp'n to Pl.'s Schenk Mot. at 23 (quoting *Yankee Atomic Elec. Co. v. United States*, 536 F.3d 1268, 1273 (Fed. Cir. 2008)). The government contends that Ms. Schenk's reference to an "economically meaningful difference" was meant to convey that "if everything worked out exactly the same way in the absence of a breach, then there would be no damages because there would be no different economic position." *Id.* at 22 (quotations omitted) (quoting Ex. 3, (Schenk Dep. Tr. at 159:7-16). Gilead contends that the correct standard is that it must "demonstrate the benefits it expected to receive had the breach not occurred." Pl.'s Schenk Mot. at 19 (quotations and brackets omitted) (quoting *Glendale Fed. Bank, FSB v. United States*, 239 F.3d 1374, 1380 (Fed. Cir. 2001)). The court will determine whether this is a true difference in standard or whether it is merely a semantical disagreement, but only upon a full presentation of the evidence. As such, Gilead's motion *in limine* is DENIED in this regard.

(iii.) Accrual of damages.

Gilead also seeks to exclude Ms. Schenk's opinion on when damages accrued. Pl.'s Schenk Mot. at 19-20. Specifically, Ms. Schenk is of the opinion that "reliance and restitution damages based on the cost or value of the material transferred under the MTAs and CTAs were reasonably foreseeable at the time the contracts were entered and that both forms of damages could be quantified to a reasonable degree of certainty by the time each of the contracts were allegedly first breached." Def.'s Opp'n to Pl.'s Schenk Mot. at 24. In its opinion denying the government's second motion to dismiss, the court held that "Gilead's claimed damages include licensing costs, but it does not follow that Gilead began incurring these damages upon the filing of the patent applications. The company only began to incur damages in the form of licensing costs once the PTO had issued the patents." *Gilead Sciences*, 155 Fed. Cl. at 343 (internal citations omitted).

"[A] decision on a motion to dismiss for lack of jurisdiction is not a judgment on the merits," *Arono, Inc. v. United States*, 49 Fed. Cl. 544, 548 (2001), and "does not foreclose, as the law of the case, the court's later consideration of those claims," *Athey v. United States*, 123 Fed. Cl. 42, 50 (2015), *aff'd on other grounds*, 908 F.3d 696 (Fed. Cir. 2018). The court's prior decisions are not dispositive rulings on the merits, and the court's ruling on the timing of damages was based on the pleadings with a presumption that plaintiff's representations were true. *See Gilead Sciences*, 155 Fed. Cl. at 341. The government is entitled to present evidence on the issue at trial where Gilead bears the burden of proof without a presumption in its favor.

As for Gilead's substantive challenge of Ms. Schenk's opinion, the government avers that she did not apply a temporal requirement for determining the quantifiability of damages to a reasonable degree of certainty. Def.'s Opp'n to Pl.'s Schenk Mot. at 25-26. "A claim first accrues for purposes of 28 U.S.C. § 2501 when all the events have occurred which fix the

liability of the [g]overnment and entitle the claimant to institute an action." *Alder Terrace, Inc. v. United States*, 161 F.3d 1372, 1377 (Fed. Cir. 1998) (internal quotation marks omitted). "A claim for breach of contract based on a failure to act first accrues when: (1) performance is due, and (2) the plaintiff suffers damages as a result of nonperformance." *Westlands Water Dist. v. United States*, 109 Fed. Cl. 177, 210-11 (2013) (internal citations omitted). Where a claim accrues beyond the six-year period permitted by § 2501, "recovery for any damage" from the claim is "barred under the statute of limitations rather than only the damage which occurred more than six years prior." *Biloxi Marsh Lands Corp. v. United States*, 152 Fed. Cl. 254, 270-71 (2021) (citing *Boling v. United States*, 220 F.3d 1365, 1373 (Fed. Cir. 2000)). Gilead recognizes that Ms. Schenk correctly acknowledges that foreseeability is evaluated at the time of contracting but alleges that her deposition revealed her analysis did not actually follow that approach. Pl.'s Schenk Mot. at 21. The truth of that assertion can be elucidated at trial but will not serve as grounds to exclude Ms. Schenk's testimony at this time. Gilead's motion *in limine* to exclude the testimony of Ms. Schenk as to accrual is DENIED.

(iv.) Causation.

Another one of Ms. Schenk's purported opinions is that it was "Gilead's decision to dispute the validity of the patents at the PTAB and in the Delaware Litigation" that caused any damages, not the alleged breach. Def.'s Opp'n to Pl.'s Schenk Mot. at 26 (quoting Pl.'s Schenk Mot., Ex. B, ¶ 142). The court is skeptical of this opinion. The government, however, argues that Ms. Schenk's analysis "is relevant to the issue of whether a causal nexus exists between the alleged breaches of the MTAs and Gilead's claimed damages." *Id.* at 27. While this trial is focused on the issue of liability, damages are an element of the case that Gilead is responsible for showing. *See San Carlos Irrigation*, 877 F.2d at 959. That the alleged breach is the but-for cause of the alleged damages is inherent to proving that some kind of damage occurred. The court will not preclude the government from presenting evidence to support its interpretation of the MTAs and the causal nexus between the alleged breach and damages. As such, Gilead's motion *in limine* to exclude Ms. Schenk's testimony on this ground is DENIED.

(v.) Quantification of damages.

When first setting a schedule in this case, the parties disagreed on whether bifurcation of the issues was appropriate, with Gilead arguing that bifurcation was necessary to prevent prejudice to its case, Hr'g Tr. 6:13-22 (April 6, 2021), and the government arguing that the issues of liability and damages were inexplicably intertwined, Hr'g Tr. 22:2-8 (April 6, 2021). The court ultimately bifurcated "liability from damages on the assumption that the liability trial w[ould] have some indication of damages so that [the trial is] not a waste of time." Hr'g Tr. 26:1-5 (April 6, 2021). Gilead now seeks to exclude portions of Ms. Schenk's testimony regarding the quantum of damages during the liability phase of the case. Pl.'s Damages Mot. at 1. It argues that it should only be required to show "the kind of damages it sustained" as a result of the government's alleged breach, Pl.'s Damages Mot. at 2 (emphasis omitted), and that the government should be prevented from presenting evidence related to the amount and quantification of damages at this point in the litigation, *id.* at 6-7. The government responds that Ms. Schenk's opinions are not about the actual quantification of damages but are directed to "the *ability* to quantify certain types of damages to a reasonable degree of certainty." Def.'s Opp'n to Pl.'s Damages Mot. at 9, ECF No. 85.

An expert's testimony must be both relevant and reliable. *See Daubert*, 509 U.S. at 579. The court discussed *supra* that it deems Ms. Schenk's experience to be sufficient to render her opinions worthy of consideration. Ms. Schenk's testimony on the ability to quantify damages is relevant even at this stage of the case. "Evidence is relevant if . . . it has any tendency to make a fact more or less probable" and "the fact is of consequence in determining the action." Fed. R. Evid. 401; *see also* Fed. R. Evid. 402 (relevant evidence is admissible unless barred by some source of law). Relevancy has a low threshold. *See Daubert*, 509 U.S. at 587 ("The Rule's basic standard of relevance thus is a liberal one."). The Federal Circuit has held that when assessing damages "it is preferable to apply a measure of damages that can be reasonably determined, as against a measure that cannot be established with reasonable certainty." *First Nationwide Bank v. United States*, 431 F.3d 1342, 1352 (Fed. Cir. 2005). Although the issue before the court at this time is liability only, damages are essential to proving liability. *See San Carlos Irrigation*, 877 F.2d at 959. While Gilead need only show an indication of damages, Hr'g Tr. 26:1-5 (April 6, 2021), inherent in that showing is that damages are reasonably determinable. Therefore, Gilead's motion *in limine* to exclude Ms. Schenk's testimony as to the "quantification" of damages is DENIED.

B. Ms. Schenk's Supplemental Report

Gilead seeks to strike a two-page supplemental report by Ms. Schenk proffered after the due date for expert reports, and exclude any related testimony at trial as untimely and prejudicial. On June 25, 2020, the Delaware court set a schedule outlining that opening expert reports would be due March 18, 2022, rebuttal reports would be due May 17, 2022, and reply reports would be due on June 16, 2022. *See* ECF No. 27, ¶ 8(a), (f), *United States v. Gilead Sciences, Inc.*, C.A. No. 19-2103MN (D. Del. June 25, 2020). This court set a deadline of April 21, 2022, for expert discovery. *See* Order of April 6, 2021, ECF No. 26. On May 25, 2022 (after the expert deadline in this case), the government served Gilead with a supplemental expert report from Ms. Schenk. The report purports to offer "new opinions based on 'expert reports submitted in the Delaware Litigation.'" Pl.'s Mot. to Strike at 3 (quoting *id.*, Ex. 1 (Schenk Supplemental Rep.) ¶ 1). None of the experts on which Ms. Schenk offers this new testimony submitted reports in this case, but instead they provided reports only in the Delaware case. These experts are not on either party's witness lists in this case, and they will not be testifying before the court in the upcoming trial. *See* Pl.'s Mot. to Strike at 4. The government responds that Ms. Schenk's short supplemental report "1) identifies representations that Gilead has made to the Delaware court and 2) describes how those representations contradict Gilead's contentions in this matter but support Ms. Schenk's opinion as presented in her expert reports." Def.'s Opp'n to Pl.'s Mot. to Strike at 2-3 (emphasis omitted), ECF No. 99.

Rule 26 of the Rules of the Court of Federal Claims ("RCFC") requires disclosure of expert testimony to be "at the times and in the sequence that the court orders." RCFC 26(a)(2)(D). "The parties must supplement these disclosures when required under RCFC 26(e)." RCFC 26(a)(2)(E). RCFC 37(c)(1) "requires exclusion of a late-filed report 'unless the failure was substantially justified or is harmless.'" *Jicarilla Apache Nation v. United States*, No. 02-25L, 2011 WL 5402932, at *2 (Fed. Cl. Nov. 7, 2011) (quoting *Tenbarge v. Ames Taping Tool Sys., Inc.*, 190 F.3d 862, 865 (8th Cir. 1999)). "Courts generally employ a multi-factor test in deciding whether exclusion under Rule 37 is appropriate, focusing on: (i) the importance of the expert testimony to be possibly excluded; (ii) the offering party's explanation for failure to disclose; (iii) the potential prejudice created by permitting the use of the expert testimony at trial;

and (iv) the ability to cure any prejudice by granting a continuance." *Id.* Yet, RCFC 26 expressly "envision[s] that a party may supplement a prior expert report." *Id.* at *1.

The government contends that the supplemental report contains relevant information as to whether Gilead has suffered the claimed harm and points to allegedly inconsistent positions Gilead is taking between this court and the District of Delaware. Def.'s Opp'n to Pl.'s Mot. to Strike at 6-8. It also argues that its filing was not untimely and that Gilead can suffer no prejudice from the report, which contains information it has put forward. *Id.* at 8. These arguments are accepted, and Ms. Schenk's supplemental report will not be excluded. The motion to strike is DENIED.

C. Testimony Regarding Evidence of Notice

A salient issue to be decided at trial is whether the government breached the relevant MTAs by failing to provide adequate notice to Gilead of any "inventions" resulting from the MTAs. Gilead seeks to preclude the government from introducing "third-party publications, documents that the government disseminated publicly, opaque and unrelated communications, and any related testimony, as evidence that it satisfied its contractual obligation to promptly notify Gilead of any inventions that were made, conceived, or reduced to practice pursuant to the parties' [MTAs]." Pl.'s Notification Mot. at 1 (quotations and brackets omitted).[8] It argues that the evidence of "[p]assive or incidental references to the patent applications" is "irrelevant, confusing, and misleading." *Id.* The government controverts this argument, claiming that the cited evidence goes directly to the issue of whether the government satisfied its contractual obligation to notify Gilead of any inventions resulting under the agreement, albeit indirectly.

Federal Rule of Evidence 403 allows the court to "exclude relevant evidence if its probative value is substantially outweighed by" unfair prejudice, the risk of confusion, or wasting time. Fed. R. Evid. 403. "However, the exclusion of evidence under FRE 403 'is an extraordinary remedy which should be used only sparingly since it permits the trial court to exclude concededly probative evidence.'" *Banks v. United States*, 93 Fed. Cl. 41, 50 (2010) (quoting *United States v. Merrill*, 513 F.3d 1293, 1301 (11th Cir. 2008)). Gilead urges that the government cannot meet its burden to prove the relevance of the challenged evidence, *see* Pl.'s Reply to Pl.'s Notification Mot. at 2 (citing Charles A. Wright & Arthur R. Miller, Fed. Prac. & Proc. Evid. § 5166 (2d ed. 2022)), ECF No. 90, but the relevance of the documents is evident, although not explicit. Relevancy is a liberal standard. *See Daubert*, 509 U.S. at 587. Whether the government satisfied its contractual obligation under the MTAs to provide prompt notification is one of the key questions in this case, making evidence the government would offer to prove it gave notice relevant. What weight the court should give such evidence is another matter, but the court will not make that determination before first hearing the evidence. Gilead's motion *in limine* to exclude evidence regarding prompt notification is DENIED.

[8] Gilead specifically seeks to exclude: a CDC technology brochure that refers to a patent application, two versions of a draft article written by the named inventors, an email summarizing the article, an invention agreement completed by one of the named inventors, a 2008 curriculum vitae of a named inventor, an internal Gilead email summarizing patent publications, the 2014 publication in the Federal Register of the non-provisional application, and emails between the CDC's technology transfer office and a Gilead employee. Pl.'s Notification Mot. at 4-9.

CONCLUSION

For the reasons stated, the motions *in limine* before the court are each DENIED. Gilead's motion to strike the supplemental report of Ms. Schenk is also DENIED.

It is so **ORDERED**.

s/ Charles F. Lettow
Charles F. Lettow
Senior Judge